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for the ESO Stroke Unit Certification Committee

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European Stroke Organisation Recommendations to Establish a Stroke Unit and Stroke Center

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In the recent Helsingborg declaration, acute organized stroke unit care was described as the backbone of the chain of care for all European stroke victims. Access to stroke units is, however, still limited. To improve the availability and the quality of affordable stroke care, the European Stroke Organisation (ESO) has appointed an ESO Stroke Unit Certification Committee to define the requirements and criteria for official certification as ESO Stroke Units and ESO Stroke Centres based on scientific evidence from randomized controlled trials, clinical practice guidelines, and expert consensus. Important features of modern stroke care include the presence of a dedicated stroke unit ward, a multiprofessional team approach, a comprehensive stroke unit organization, including emergency room organization, adherence to diagnostic and therapeutic time-windows, early swallowing diagnostics and therapy, intravenous thrombolytic therapy, periods of automated monitoring, access to decompressive craniectomy and intraarterial thrombolysis, early mobilization and rehabilitation, supported discharge and basic aftercare with treatment of risk factors and poststroke prevention. The Committee defined the target population, the necessary infrastructure, technical equipment, diagnostic pathways, therapeutic interventions, nursing care, and multiprofessional rehabilitation. The definitions also cover the hospital environment characteristics and the stroke unit's interactions with other departments. Quality indicators for benchmarking are presented. Although the ESO Stroke Unit's requirements are largely evidence-based, expert consensus is also included where evidence was unavailable. These recommendations of the ESO task force should stimulate hospitals in Europe to apply for ESO certification. Fulfilling of the criteria will be checked by on-site visits.

Problem and Goals

Acute stroke care in hospitals is best performed in organized stroke units, which are the essential part of the chain of recovery and form the backbone of prehospital, in-hospital, and

posthospital care, that is, from home back to home. There is convincing evidence from a large number of randomized controlled trials that the outcomes of stroke and transient ischemic attack (TIA) patients managed in dedicated stroke units are better than those of patients managed in general medical or neurological wards.¹⁻³ The stroke unit model tested in randomized controlled trials forms the key basic measure of stroke service quality. More refined infrastructures have also been developed for acute diagnostics and treatment but are not defined as absolute requirements because of less substantiated evidence and higher dependence on resources.

The chain of care for TIA and stroke patients requires immediate recognition of the stroke symptoms by the patient and his environment, rapid and well-organized prehospital paramedical support, including transportation and prehospital notification to the admitting emergency room, and timely and competent in-hospital treatment at the emergency department. Stroke-trained emergency services play a key role in diagnosing the stroke symptoms and transferring the patient to the nearest available stroke unit or stroke center. The expertise of a well-trained hospital staff and postacute rehabilitation services are further prerequisites for this continuous stroke care pathway.^{1,4,5} There is also sufficient evidence that the benefits seen in stroke unit trials are replicated in routine practice, as long as these evidence-based principles of organized stroke unit care are considered in daily routine.⁶

Striking discrepancies in infrastructure and quality of stroke care, but also in costs and outcome, have been identified in Europe,^{7,8} indicating the urgent need for a common and agreed concept of well-organized evidence-based stroke care in European countries, and for standardized, methodologically sound regional or national audits of stroke care. The limited access of acute stroke patients to adequate stroke unit care in Europe was alarming and still is in many countries.⁸⁻¹⁰ These studies underline the fact that there is still a great need to improve stroke care also in those countries which have already organized their own evaluation and certification of stroke units.

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The study by Leys et al⁸ reveals that only 1 of 7 stroke patients in Europe has admission to stroke unit care, and 42% of them are treated in hospitals that have no facilities nor expertise to provide good care for stroke patients. This situation exists despite the Consensus Statements delivered at the Consensus Conferences organized by the World Health Organization European Office in 1995 and 2006 saying that all stroke patients in Europe should have admission to stroke unit care. This principle has been advocated by the European Stroke Initiative, the European Stroke Organisation (ESO), and the American Heart Association. This is why we urgently need a European consensus to define the updated evidence-based needs for acute stroke care (so-called ESO Stroke Units), and to stimulate the certification of more advanced stroke centers (so-called ESO Stroke Centers). This document is not a recommendation on how to treat stroke patients in stroke units^{5,11} but it concentrates on recommendations how to structure and organize a modern stroke unit in a continuum of care indicating what are the infrastructural components and processes of ESO Stroke Units and ESO Stroke Centers making good stroke management possible.

The main focus of this document is on the acute in-hospital management of TIA and stroke patients. Patients with intracerebral hemorrhage not needing care at an intensive care unit (ICU) can also be treated at an ESO Stroke Unit/ESO Stroke Center.^{5,11} It also considers the organization and quality of the prehospital management, as well as the guidance of the patients into the chain of postacute care, including rehabilitation and secondary prevention.^{1,5,11}

This statement is also intended to stimulate European hospitals to apply for an ESO certification guaranteeing that evidence-based infrastructural and procedural criteria of organized stroke care are met.

Based on this document, the Stroke Unit Committee proposes to certify (1) ESO Stroke Units and (2) ESO Stroke Centers. The Table provides the types of requirements for (1) ESO Stroke Units and (2) ESO Stroke Centers (see Glossary below). Although we recognize that there could be an even more advanced, staffed, and equipped, third category of Neurovascular Centers, incorporating several stroke-related medical and surgical specialties as a future option where highly specialized treatments are available for the entire spectrum of neurovascular disorders, we confine the present certification criteria to the above 2 levels of stroke unit care. The certification process will assess the infrastructure, the staffing, and the stroke management procedures based on on-site visits by independent experts. Well-defined quantifiable quality indicators (see below) will be considered as performance measures.^{12,13}

Those countries which already have a national stroke unit accreditation do not need to double their certification. It is completely up to the nationally acknowledged stroke units to apply for a complementary additional ESO certification. It could, however, contribute to a future harmonization and improvement of the care of stroke patients. The ESO does not have any plans to put sanctions on stroke units not applying for, or not passing the certification process.

Methodology

In 2007, the ESO nominated a Stroke Unit Committee (thereafter called Committee) to create a consensus document on the essential

criteria that define well-established international standards of stroke unit care and recent progress in stroke medicine, and to implement a system for the certification of stroke units in Europe. The Committee Members were appointed (1) because of their expertise in the field of stroke unit care and (2) to cover a broad spectrum of views and experiences all over Europe. The first step was to achieve consensus on essential components of an acceptable stroke unit level in Europe leading to an official certification by the ESO.

The selection of components of the ESO Stroke Unit and ESO Stroke Center is based not only on the experience of the ESO Executive Committee and ESO Stroke Unit Committee but also on a survey of European stroke experts¹⁴ who considered as important or absolutely necessary the components for a Comprehensive Stroke Center (in the present article ESO Stroke Center) and for a Primary Stroke Center (in the present article ESO Stroke Unit).

Second, a clear terminology was developed (for definitions, see below).

Third, the Committee reviewed the evidence and other recommendations for stroke unit care and its components. It then drafted an article which was reworked in several face-to-face, telephone, and email conferences. The resulting document provides a consensus statement among the members of the Committee on the design, infrastructure, and organization of organized stroke unit care recommended for all European hospitals admitting and treating acute stroke patients. It has been approved in the current version by the ESO Executive Committee.

Definition of the Terminology Used Here

1. **Must:** defines essential criteria that are compulsory for the certification based on scientific evidence (ie, evidence that is either rated as class 1 or 2 or has been classified as having high-level importance in the European Stroke Guidelines).^{5,11}
2. **Recommendations:** defines items or requirements that are expected to be present. Their absence can only be accepted in particular circumstances and are expected to be implemented. The stroke unit director should be working hard to meet this recommendation in the future and have a clear plan to achieve this.
3. **Suggestions:** defines items that should be considered as good practice points for the stroke unit. Suggestions will often be based on expert opinion or accepted good clinical practice. If they are not present in the stroke unit they should be discussed with the stroke unit director with respect to future implementation.
4. **Availability on-site:** indicates that the service (eg, equipment, facility, personnel, or procedure) is permanently present in the same department or hospital.
5. **Having access to:** indicates that the service (eg, equipment, facility, personnel, or procedure) can be obtained within an acceptable time period by making use of other in-house departments, or nearby hospitals, or institutions. Having immediate or timely access: indicates that the service has to be provided with a high priority policy within an acceptable time period (such as within 30 minutes). Because of the extreme variability of hospital infrastructure, some overlap of paragraphs 4 and 5 seems acceptable.

The Basic Concept for Effective Interventions

Three basic principles of organized stroke unit care have been proven to be highly effective in terms of improved outcome (fewer deaths, less dependency). They include (1) a dedicated stroke ward, (2) a multiprofessional team approach (in the original articles also called multidisciplinary), and (3) a system of comprehensive stroke unit care. All 3 principles are based on evidence level I.^{5,11}

Dedicated stroke ward care means that acute stroke patients (including stroke-mimics) are treated in a geographically defined area of the hospital admitting exclusively stroke and TIA patients and not patients with other disorders. The reason

Table. Facilities Necessary for European Stroke Organisation Stroke Units Compared With European Stroke Organisation Stroke Centers

	ESO Stroke Unit	ESO Stroke Center
Departments and clinics	[Multiprofessional stroke unit] [Inpatient rehabilitation (in-house)] [Outpatient rehabilitation available] [Collaboration with outside rehabilitation center] Stroke outpatient clinic	Emergency department (in-house) Multiprofessional ICU [Multiprofessional stroke unit] Inpatient rehabilitation (in-house) Outpatient rehabilitation available Collaboration with outside rehabilitation center Stroke outpatient clinic Anticoagulation clinic
Staff available	Stroke-trained physician Multiprofessional team Stroke-trained nurses Social worker	Stroke-trained physician (24/7) Multiprofessional team Stroke-trained nurses Social worker Neurologist on call Neurologist on staff Emergency department staff Physician expert in carotid ultrasonology Diagnostic radiologist on call CEA vascular surgeon Interventional neuroradiologist on call Neurosurgeon on call Physician expert in echocardiography Physician trained in rehabilitation
Investigations available	[Brain CT scan 24/7] [CT priority for stroke patients] [Extracranial duplex sonography] [Transthoracic echocardiography] [Transesophageal echocardiography]	Brain CT scan 24/7 CT priority for stroke patients Extracranial Doppler sonography 24/7 Extracranial duplex sonography Transthoracic echocardiography Transoesophageal echocardiography MRI (T1-, T2-, T2*-weighted, FLAIR) 24/7 Diffusion-weighted MRI Transcranial Doppler sonography 24/7 CT angiography 24/7 Magnetic resonance angiography 24/7 Transfemoral cerebral angiography 24/7
Hyperacute interventions	Intravenous rt-PA protocols Respiratory support Access to hemicraniectomy* Access to surgery for hematoma Access* to intra-arterial interventions	Stroke care map for patient admission Intravenous rt-PA protocols 24/7 Respiratory support Hemicraniectomy on site Surgery for hematoma on-site Intra-arterial interventions on-site Ventricular drainage on-site
SU interventions	Agreed written protocols for common problems	Stroke pathways
SU monitoring	Monitoring of heart rate Monitoring of oxygen saturation Monitoring of blood pressure Monitoring of breathing Monitoring of temperature	Automated ECG monitoring (bedside) Automated monitoring of pulseoximetry Automated monitoring of blood pressure Automated monitoring of breathing Monitoring of temperature

(continued)

Table. (Continued)

	ESO Stroke Unit	ESO Stroke Center
SU assessment	Early rehabilitation assessment** Food and fluid management Speech therapy start <2 days Physiotherapy start <2 days Dysphagia management (swallowing screened on admission) Physiological management Early mobilization Skilled stroke nursing	Early rehabilitation assessment** Food and fluid management Pathway for dysphagia management Physiological management Early mobilization Skilled stroke nursing
SU multiprofessional team care	Coordinated multiprofessional stroke unit care (care in a discrete area in the hospital, staffed by a specialist stroke multiprofessional team with regular multiprofessional meetings for planning care) Early discharge planning	Coordinated multiprofessional stroke unit care (care in a discrete area in the hospital, staffed by a specialist stroke multiprofessional team with regular multiprofessional meetings for planning care) Early discharge planning
Interventions: other	Access to surgery for aneurysms Access to carotid surgery	Surgery for aneurysms Carotid surgery Angioplasty and stenting Community stroke awareness program Prevention program Stroke clinical fellowship Stroke database Clinical research

Based on Langhorne and Dennis⁴ and Leys et al⁸.

CEA indicates carotid endarterectomy; CT, computed tomography; ESO, European Stroke Organisation; FLAIR, fluid attenuated inversion recovery; ICU, intensive care unit; MRI, magnetic resonance imaging; rt-PA, recombinant tissue plasminogen activator; and SU, stroke unit.

Items in [brackets] are not explicitly stated but are implied in the original publication.

*Access means not necessarily on-site, but defined partnership with a providing institution.

**By an appropriately trained professional.

for this principle is to specifically focus on the needs of the stroke patients and to allow the entire staff to develop expertise in stroke care.

The multiprofessional team approach implicates that stroke units must be staffed with physicians, nurses, physiotherapists, occupational therapists, speech and swallowing therapists, neuropsychologists where available, and social workers (including a case manager) with special interest, training, and expertise in stroke care. This multiprofessional stroke team must work together in an organized and systematic way and cooperate as specified by the criteria below.

The physicians are neurologists or internists provided that their focus is stroke care and that they are specifically trained in stroke medicine.

Comprehensive stroke unit care means that acute stroke management, that is, diagnostic work-up and treatment, is seamlessly combined with early mobilization and rehabilitation and secondary prevention, according to the needs of the patient (out of bed within 24-hour principle).¹⁵ The level of acute stroke care is enhanced and offers more possibilities and advanced care compared with a general ward.

According to the ESO Guidelines (revised version 2009) on stroke treatment (page 10/11), emergency care of the acute stroke victim depends on a 4-step chain: (1) rapid recognition of, and reaction to, stroke signs and TIAs, (2) immediate EMS contact and priority EMS dispatch, (3) priority transport with prenotification to the receiving hospital, and (4) immediate

emergency room triage, clinical, laboratory and imaging evaluation, and accurate diagnosis and administration of appropriate treatments at the receiving hospital.

As a general rule, treatment starts in the emergency department although direct admission into the stroke unit is an alternative in hospitals where this system speeds up the initiation of the therapy. A first evaluation of the patient in the ED can also help to preliminarily separate stroke mimics from true strokes. Once the status of the patient has stabilized, both acute medical care and secondary prevention must be merged with the early mobilization and rehabilitation measures.

Other key elements of care in a stroke unit should incorporate systematic screening and management of swallowing disorders, management of food and fluids, early assessment of impairments and rehabilitation needs and close monitoring of neurological and medical complications. In particular, swallowing diagnostics and therapy are essential to reduce the risk of pneumonia, the leading cause of death in stroke patients.^{12,15,16} Prevention, early detection, and treatment of other complications, like prevention of deep venous thrombosis and pulmonary embolism are further essentials of stroke unit management. To transfer these principles into routine clinical practice, a considerable number of infrastructural and organizational requirements must be met.

Periods of automated monitoring of physiological parameters in the acute phase have been shown to improve the outcome of stroke patients in 1 prospective pilot study¹⁷ and in

3 observational studies.^{18–20} Automated monitoring is part of routine care in many well-equipped stroke units and recommended by the ESO and several national guidelines.^{5,21} Appropriate technical and staff requirements for this facet of acute stroke unit care should also be available.

Intravenous thrombolytic therapy with recombinant tissue plasminogen activator has been proven to be highly effective, with a number-needed-to-treat ranging from 4.5 to 14.1 depending on the time delay to recombinant tissue plasminogen activator administration, that is, from within 0 to 90 minutes to 181 to 270 minutes after stroke onset, respectively.²² Infrastructural and procedural features of both the emergency room and the stroke unit must meet the needs to fully implement this stroke-specific therapy. A population-based analysis revealed that 24% of all ischemic stroke patients are potential candidates for intravenous thrombolytic therapy within the 3-hour time window if no delay in patients' processing would occur.²³ This has already become reality, for instance at the Helsinki University Central Hospital in Helsinki, Finland, which is the only acute neurological emergency room serving a population of 1.5 million inhabitants on 24/7 basis. Here, 31% of all ischemic stroke patients (357/1151) were treated with thrombolysis in 2011.²⁴ In Helsinki, the indications for thrombolysis are based on the updated ESO recommendations, as well as those approved by the European regulatory authorities and those approved by the American regulatory authorities. By contrast, a recent survey of 868 hospitals in 25 European countries revealed that on average only 3.3% of all acute ischemic stroke patients have access to thrombolysis.⁸ The frequency of thrombolytic treatment directly depends on the availability and the organizational level of stroke unit care.¹⁰ All ESO Stroke Units must not only be able to deliver thrombolysis in due time but also have timely access to other acute recanalizing interventions (for instance, intra-arterial procedures, although not necessarily on-site). Timely access to interventional thrombectomy in the nearby stroke center would suffice.

Intra-arterial thrombolysis within 6 hours of the onset of acute ischemic stroke significantly improved clinical outcome at 90 days in middle cerebral artery occlusion in selected patients.²⁵ Intra-arterial retriever devices have also been shown to effectively recanalize occluded arteries but there is no randomized controlled trial yet to show that this therapy is safe and effective. This treatment is recommended only within the context of an ESO Stroke Center and should be based on evidence when it comes available. The treatment must adhere to a protocol documenting complications and outcomes. The treatment must be based on previous experience with devices for stroke treatment.

Decompressive craniectomy in patients with malignant middle cerebral artery infarction, or other rapidly space-occupying infarcts, has also been shown to be highly effective in selected patients up to the age of 60 years, if performed early enough (number-needed-to-treat for survival = 2).²⁶ ESO Stroke Centers should have this therapy available within their hospital.

The ESO Stroke Unit care concept will also be open for future development, and new diagnostic and therapeutic

achievements. Innovations should be implemented as soon as there is strong enough evidence for their clinical use and cost-effectiveness.

This document provides a consensus statement among the members of the ESO Stroke Unit Committee on the design, infrastructure, and organization of organized stroke unit care recommended for all European hospitals admitting and treating acute stroke patients.

Acute Stroke Unit Care Requirements

Target Population

The benefit of organized stroke unit care covers all groups of stroke patients,³ including hemorrhagic and ischemic stroke. There is also no indication that age or sex limits the benefits of organized stroke unit care. Indeed, elderly patients and those with severe stroke benefit most of stroke unit care.²⁷ Alternatively, patients requiring vital support (artificial ventilation, shock treatment, septic complications, polytrauma, etc) require admission and care on an ICU. The target population of ESO Stroke Unit management also includes TIA patients whenever a TIA clinic is not available. Stroke units are presently the most appropriate and practical solution for TIA patients. Advanced imaging has shown that up to half of clinically defined TIA patients experience a brain infarct, and they are highly prone to early stroke recurrence.²⁸ TIA patients considered to be at high risk of early stroke recurrence should, in particular, be treated in a stroke unit,²⁸ to perform early pathogenetic diagnosis, implement a very early secondary prevention or initiate thrombolytic therapy without delay in case of stroke recurrence.

The target population of an ESO Stroke Unit also includes patients with cerebral venous thrombosis. It is also appropriate to treat patients with subarachnoid hemorrhage not requiring intensive care treatment, in a stroke unit in close cooperation with a neurosurgeon or neurointerventionalist. This may vary from region to region according to local practice, facilities, and local agreement.

We can expect that some stroke mimics will erroneously be admitted into the stroke unit,²⁹ and therefore they should be discharged as soon as the true nature of their disorder has been ascertained.

The benefits of stroke unit care may decline over time elapsed since stroke onset, and preferably acute stroke patients should be admitted acutely. Although a specific time limit cannot be established, patients should not be excluded from stroke unit care simply because of delayed presentation, particularly if the clinical condition of the patient requires a closer attention that cannot be provided at general wards. Stroke patients presenting late require the same diagnostics, early rehabilitation, secondary prevention, and prevention of complications as those patients presenting early.

Two Levels of Organized Stroke Care

The Committee has established 2 certification levels: (1) ESO Stroke Units and (2) ESO Stroke Centers. ESO Stroke Units must meet updated evidence-based requirements. A minimum set of criteria will be defined that must be fulfilled by all

hospitals willing to achieve ESO Stroke Unit Certification to provide evidence-based care for stroke patients.

Hospitals with more advanced equipment, higher staffing, and more diversified and larger resources should apply for ESO certification as ESO Stroke Centers, although some of them might simultaneously serve as primary centers for stroke patients from their own catchment area. They must meet all the requirements of an ESO Stroke Unit, and additionally should provide more advanced diagnostic and therapeutic equipment, have a larger staff and have expertise on rare or complex stroke subtypes. These additional recommendations of the Committee will be based on level II evidence from the literature, as well as on expert recommendations.⁸

The ESO certification procedure should refer to the stroke unit as such, not the department and not the hospital either, although simultaneously taking the entire setting into consideration.

ESO Stroke Unit

Stroke unit criteria are organized along 7 fields of action (1) to ensure vital functions, (2) to provide early diagnostic investigations, (3) to allow basic surveillance and (4) stroke-specific therapeutic interventions, (5) to perform general therapeutic and diagnostic interventions, (6) to start secondary prevention, and (7) to combine this with multiprofessional early mobilization and rehabilitation procedures.

Infrastructure of the ESO Stroke Unit

A swift transfer from the emergency department to the acute monitored beds of the stroke unit must be guaranteed. Use of a clinical pathway will be checked by the on-site visit.

The stroke unit should consist of 2 functional parts operated by the same team. Part or segment A refers to the acute stroke monitoring period, and part or segment B constitutes the postacute step-down stroke unit.⁴ Based on expert consensus, in the acute stroke monitoring part, at least 4 beds are a minimum, providing 24-hour continuous monitoring of vital parameters (ECG, blood pressure, O₂-saturation, and temperature). The postacute step-down stroke unit segment B should include twice the number of monitored beds as part A. However, the number of beds and the length of stay on the postacute step-down stroke unit should be sufficient to accommodate the expected number of stroke admissions in the catchment area per year, and may vary locally depending on how many hospitals with a stroke unit admit acute stroke patients regionally, how these admissions are shared between the hospitals, and on local variations in access to rehabilitation beds and nursing home care. One monitored bed is recommended per 100 patients per year because the average stay on monitoring has been calculated to be 72 hours.²¹

Most patients should initially be admitted to the monitored stroke unit beds until stabilization. This means a minimum monitoring phase of 24 hours (except for stroke mimics), but may be longer according to the needs of the patients. After the monitoring period, patients are shifted to the postacute step-down stroke unit beds within the same ward for further management, diagnostic work-up, secondary prevention and, particularly, continuation of their early mobilization and rehabilitation. This set up is mandatory, that is, the acute stroke

monitoring beds, as well as the nonmonitored beds, are geographically embedded within the same stroke unit and managed by the same multiprofessional stroke unit team. A smooth transfer from the monitored stroke unit beds to the other beds shall be organized. This concept has advantages because it avoids mixing stroke patients with patients experiencing other neurological disorders and maintains the dedicated principle and continues the multiprofessional approach.

Early Diagnostic Investigations

Urgent access to a neurological evaluation and to the expertise of a neurologist or internist experienced in stroke medicine (including experienced residents or fellows) must be available within 30 minutes of hospital admission on a 24/7 basis.

Frequent neurological checks are important in detecting alarming changes in the condition of the patient. Clinical evaluation of the severity of the stroke by a standardized neurological impairment scale is required, preferably the Neurological Institute of Health Stroke Scale performed several times per day.

Urgent diagnostic differentiation of ischemic stroke, cerebral hemorrhage, subarachnoid hemorrhage, or cerebral venous thrombosis obtained by brain imaging is mandatory. At least a brain computed tomography (CT) scan must be performed to distinguish between ischemic and hemorrhagic stroke.⁵ The Committee suggests a one-stop diagnostic procedure, including a CT perfusion scan when indicated as has recently been reported,³⁰ and a contrast medium-based CT angiography, including cervical arteries^{31,32} when appropriate and available.

A CT scanner providing ≥ 64 lines is recommended for ESO Stroke Units. Alternatively, a magnetic resonance imaging (MRI) with a magnetic resonance angiography and perfusion imaging can be performed according to ESO recommendation.⁵ An initial MRI of the brain is particularly helpful for identification and exclusion of stroke mimics to save stroke unit resources.

Diagnostic and Therapeutic Infrastructure

The following facilities and procedures must be provided when appropriate:

1. A CT scan or MRI must be performed within 30 minutes of hospital admission in all acute stroke patients. Decisions on the use of CT or MRI should be based on the ESO recommendations and guidelines and must be left to the physicians in charge.
2. Permanent access to ECG at any time. The initial ECG must be performed rapidly after arrival in the hospital. To identify patients with acute myocardial infarction^{33–35} every patient must receive an initial 12-lead ECG as soon as possible but without delaying acute stroke treatment. Approximately 3% of acute stroke patients have elevated troponin T levels and electrocardiographic changes, suggesting myocardial infarct.³⁶
3. Availability of Doppler (continuous and pulsed wave Doppler sonography with opportunity to monitor for microembolic signals) and color-coded duplex ultrasonography on-site within ≤ 24 hours of admission. If CT/MR-angiography has been done, the role of ultrasound

studies is complementary, for example, to follow-up the causative arterial lesion, to monitor microembolic signals, or to pinpoint ulcerated carotid plaques, etc. Transcranial Doppler makes it possible to detect when thrombolysis recanalizes the occluded artery. It also allows to ensure that cerebral blood flow stays at adequate level.

4. Access to a transesophageal echocardiography and transthoracic echocardiography for the detection of cardiac comorbidities and cardiac or aortic sources of embolism. Either technique must be available 7 days a week during working hours. An agreement with the department of cardiology must be documented.
5. Access to imaging confirmatory tests for cerebral artery stenosis or occlusion, or venous sinus thrombosis.
6. Optional access to MRI imaging.
7. Permanent immediate access to ICU with state-of-the-art equipment for vital support (including continuous monitoring of ECG, oxygen saturation, invasive or non-invasive measurement of blood pressure, ventilatory assistance, and intubation when deemed necessary).
8. In candidates for specific stroke interventions, like intravenous thrombolysis or intra-arterial fibrinolysis, 24/7 laboratory test results shall be available on-site within 20 minutes after blood sampling (platelet count, prothrombin-time, and international normalized ratio).⁵
9. The door-to-needle time should be no longer than 60 minutes and preferably should be maintained as short as possible trying to achieve the ambitious time of ≤ 30 minutes.^{24,35,37,38}

There is still the need for digital subtraction angiography in certain patients (eg, granulomatous angiitis of central nervous system, and if an intra-arterial intervention is planned). Written protocols with the radiology department for timely on-site access to these services must exist.⁵

Initial Monitoring

Continuous automated monitoring of physiological parameters, including oxygen saturation, arterial blood pressure, heart rhythm and ECG (1-lead), body temperature, and intermittent monitoring of blood glucose, must be available immediately. Continuous or frequent monitoring of these parameters is recommended in all acute stroke units.

Close-meshed follow-up of the neurological status of the acute stroke patients is necessary for rapid detection of neurological or medical complications, or stroke recurrence according to the guidelines.⁵ This should best be documented by means of the Neurological Institute of Health Stroke Scale.

Therapeutic Interventions

Every ischemic stroke patient must be evaluated on admission for appropriateness of intravenous thrombolysis according to the current guidelines.^{5,39,40} In patients who are suitable candidates for intravenous thrombolysis, the target door-to-needle time should be <60 minutes at any time.^{35,37,38} The ESO Stroke Unit Committee recommends a maximum of 30 minutes to obtain and analyze the CT.^{35,41} The Committee suggests that ESO Stroke Units should have permanent access to intracranial interventions by collaborating with an ESO Stroke Center.

Stroke units should have timely access to hemicraniectomy 24/7 either in-house or in other hospital reachable within 30 minutes.

For hemorrhagic stroke, there is still limited evidence-based treatment available. The value of neurosurgical evacuation of intracerebral bleedings or hemicraniectomy is still undefined, but should be discussed with neurosurgeons in special cases on the basis of the Surgical Trial in Lobar Intracerebral Haemorrhage I (STICH I) Study.⁴² In the Intensive Blood Pressure Reduction in Acute Cerebral Haemorrhage Trial I (INTERACT I), the achieved on-treatment systolic blood pressure level within the first 24 hours after stroke onset was associated with absolute and proportional hematoma growth reduction with an optimum attenuation of hematoma growth at systolic blood pressures of 130 to 140 mm Hg.⁴³ This was particularly true for very early intensive blood pressure lowering.⁴⁴ This dose-dependent, positive influence on 3-month outcome has recently been confirmed.⁴⁵ Whereas the trial on direct procoagulant therapy with activated factor VII was negative,⁴⁶ patients with intracranial bleeding during oral anticoagulation should be treated with fresh frozen plasma or prothrombin complex concentrates⁴⁷ according to the available guidelines.

General medical treatment of fever, hyperglycemia, blood pressure, fluid balance, etc should be performed according to guidelines.

Secondary stroke prevention should be installed as early as possible, and preferably within the first 24 hours after admission according to the guidelines.⁵

Basic Nursing Care

Stroke units must have specialized nursing dedicated to stroke patient care. Nurses need to be trained specifically in stroke medicine in a formal way. Nursing care focuses on careful positioning and handling of the patient according to the guidelines with pressure-area risk evaluation, neurological monitoring by means of scales, fluid balance assessment, monitoring of excretions and body temperature, and assessment of dysphagia. This treatment aims particularly at the prevention and early detection of complications like aspiration pneumonia, deep venous thrombosis, pressure sores, and dehydration.

Nurses should also involve patient's next to kin and caregivers in the training and care at home, and they should provide information on stroke, stroke recovery, and poststroke services, including access to stroke patients support organizations.

Multiprofessional Mobilization and Rehabilitation

A multiprofessional team must provide continuous daily services as needed, tailored to the specific needs of the individual patient on 7 days per week:

1. Mobilization and rehabilitation closely linked with nursing care.
2. Early mobilization of the patient according to out of bed within 24-hour principle as soon as the stroke has stabilized and the general medical condition and stroke severity make this possible.
3. Early mobilization and physical therapy at least once daily (7/7) and, if resources make it possible, preferably twice a day, adapted to the medical condition of the patient.

4. Formal multiprofessional team meetings allowing every patient to be evaluated at least once.
5. Therapeutic goal setting.
6. Assessment of activities of daily living and occupational therapy.
7. Systematic screening and management of swallowing disorders.
8. Speech and language therapy.
9. Neuropsychological assessment and cognitive rehabilitation.
10. Information to patients and their carers (proxies) about diagnostics, therapies, rehabilitation, and prognosis at all times.
11. Discharge planning (in cooperation with social worker).

Patients not capable of active or even passive mobilization attributable to their medical condition may be excluded for a limited time from these procedures, or part of them.

Hospital Characteristics Necessary to Run the ESO Stroke Unit

1. A laboratory must be operative and provide all basic tests 7/24.⁵
2. Radiology service with at least modern multislice CT scan technology. This imaging technology should be based on a multidetector system to allow noninvasive arteriographies and venographies, as well as perfusion CT (≥ 64 slices recommended). A ≥ 64 slices scanner is recommended for ESO Stroke Units and required for ESO Stroke Centers.
3. Access to MRI and to 7/7 digital subtraction angiography is needed for ESO Stroke Units, but not necessarily on-site.
4. Emergency department operating 24/7 on-site.
5. ICU on-site.
6. Cardiology service on-site with transesophageal echocardiography technology available at least during working hours, and transthoracic echocardiography on a 24/7 basis.
7. Extracranial and intracranial ultrasonography laboratory (technical level: color-coded duplex sonography) available on a 24/7 basis.

Medical and Nursing Staff Expertise

All medical and nursing staff should have ongoing training in stroke management, that is, continuous medical education for each profession as appropriate, at least once a year. Itineraries and participation lists must be presented on request.

Before the medical and nursing staff are allowed to work independently, formal practical training on acute stroke unit care is required and should be provided.

The multiprofessional stroke team is headed by a stroke unit (center) director who must be a stroke-trained physician, responsible for organizing the stroke care pathway and the stroke unit as its core element.

The stroke unit or stroke center director (physician)

1. must have at least 1 year of relevant neurological training during residency and 1 year of stroke medicine where available, but should preferably be a board certified neurologist, or qualified correspondingly.
2. must have been trained in a stroke unit for at least 6 months in a nonleading position.

3. must achieve 5 credit points of continuous medical education (continuous medical education credits) each year in the area of cerebrovascular diseases where available.

Both neurologists and non-neurologists must have knowledge of cerebrovascular diseases to provide leadership and guidance to the program. The main focus of the physician on the stroke unit should be the care of stroke patients.

ESO organizes a 2-year academic education program leading to the master of science degree in stroke medicine. So far, the number of these experts is, however, quite modest, and other educational tracks for physicians to become stroke-trained are necessary. The ESO Stroke Unit Certification Committee has decided to recommend a quite short curriculum for stroke physicians and stroke unit directors knowing well that even that is hard to accomplish in many European countries.

Stroke Emergencies

For reasons of continuity, a stroke unit/stroke center team requires at least 2 stroke physicians. During working hours the activity of at least 1 stroke physician of the stroke team has to be dedicated to the stroke unit/stroke center and for the patient care and management there.

Outside the working hours, one of them is on call around the clock and must be able to be on site within 30 minutes, also on the weekends for adequate, 24-hour, rapid response, and for medical cover of emergencies.

Consultation of a stroke-trained physician should be available on a 24/7 basis and, when needed, the stroke physician must be on the spot within 30 minutes.

A neurosurgeon does not need to be available on-site. He/she can be consulted around the clock and can provide rapid consultation within 2 hours, either on-site or by telemedicine. A written agreement with a neurosurgical team either on-site or from a nearby hospital is required.

A written protocol is necessary describing the handling of patients requiring neurosurgical expertise to ensure a rapid response to cover neurosurgical stroke emergencies.

Vascular surgical services do not need to be available on-site. A vascular surgeon should be consulted within 72 hours. A written agreement with the vascular surgeon from a nearby hospital to provide vascular surgical services is sufficient. A written protocol is available describing the handling of patients requiring vascular surgical expertise. When indicated, carotid endarterectomy must be accessible within 2 weeks of stroke onset of cerebrovascular symptoms related to a carotid disease.

Symptomatic patients not suitable for carotid endarterectomy should have access to carotid angioplasty/stenting within the same time frame as an alternative treatment.

A cardiologist must be available on-site for consultation on 24/7 basis.

Nonmedical Staff and Expertise

The multiprofessional team consists at least of

1. a physiotherapist on full-time job,
2. an occupational therapist,

3. a speech and swallowing therapist,
4. a social worker, and
5. a clinical neuropsychologist where available.

These professionals must be available on-site during each working day, even if they are not dedicated to the stroke unit/stroke center full-time. In stroke units with step-down beds, patients stay longer, and the team must meet at least once a week to discuss goal-setting and individual progress of the stroke patients. The time and content of the meeting must be documented. However, during the hospital stay, each patient should be discussed and evaluated at least once at a multiprofessional meeting for assessment of medical and functional prognosis, appropriateness of current and future treatments and neurorehabilitation, individual goal-setting, and discharge planning.

The amount of early mobilization and rehabilitation therapy should be assessed and adapted to the needs of the individual patient. Descriptive examples have been published.⁴⁸⁻⁵⁰ There is a direct relationship between the intensity of therapy and outcome.^{51,52} Written protocols should be available.

Nurse Staffing. Because of the high nursing requirements of stroke patients, 1.5 nurses per monitoring bed constitute the minimum staffing referring to 24-hour duty rota. This means, for example, 6 fulltime equivalent nurses in the team for 4 monitored beds. The corresponding numbers for nonmonitored beds are 0.5 full-time equivalent nurses on 24-hour duty rota, which means, for example, 2 additional full-time equivalent nurses in team for 4 nonmonitored beds. These numbers match the recommendations of various Intensive Care Medicine authorities on the minimum staffing of intermediate care beds per shift. The Australian College of Critical Care Nurses Guidelines require a minimum of 1:1 for ventilated and other critically ill patients, and 1:2 nursing staff for lower acuity patients.⁵³ Quite similarly, Adomat and Hewison⁵⁴ defined the agreed nurse:patient ratio for category 1 patients, which fits best the clientele on a stroke unit, as follows: the patient is considered to be in need of high-dependency-units (HDU) care. The expectation is that 1 nurse can care for 2 patients. The European Society of Cardiology recommends 1.8 nurses per bed for intermediate cardiac care.⁵⁵

Step-down Rehabilitation

The hospital certified for the stroke unit care program, which does not have its own rehabilitation beds within their own department, must have a written agreement with at least 1 rehabilitation department/hospital to smoothly transfer their stroke patients who need stationary rehabilitation to that facility after the acute stroke unit care phase. A similar written agreement is required for those patients who can be rehabilitated at outpatient rehabilitation clinics.

Minimal Volumes and Activities

To ensure an acceptable level of expertise and quality, the stroke unit must admit an average of at least 200 stroke or TIA patients per year to their acute stroke unit ward. Mortality was significantly lower in hospitals treating more than 200 patients per year.⁵⁶ The documentation of the last 6 months will be used for certification.

On average, at least 16 patients per year shall be treated by intravenous thrombolysis within the first 3 (or 4.5) hours.^{12,57}

Cooperation of ESO Stroke Units With ESO Stroke Centers
Patients requiring the more sophisticated elements and logistics of an ESO Stroke Center should be transferred to these facilities (see below). Written pathways must document this collaboration.

The ESO Stroke Center

For ESO Stroke Centers, additional requirements are mandatory on top of the requirements for ESO Stroke Units. Requirements for ESO Stroke Units have been detailed in the ESO Stroke Unit section and have also been detailed in the Table.

MRI On-Site

ESO Stroke Centers, but not ESO Stroke Units, require on-site availability of MRI of the brain on a daily 24-hour basis. MRI is necessary to diagnose brain infarction in CT-critical areas, like the posterior fossa, and it is also necessary for the detection of small strategic infarctions, or small, new infarctions in the context of a severe leukoaraiosis.⁵⁸ MRI is also important for the diagnosis of cerebral venous thrombosis, intramural hematoma in cervical artery dissection, congestive encephalopathy attributable to arteriovenous fistulas, cavernomas and other arteriovenous malformations, spinal cord infarctions or hemorrhages, and to identify stroke mimics.

Additional Medical Services On-Site

ESO Stroke Centers should provide additional 24/7 services in neurosurgery, vascular surgery, invasive cardiology, as well as diagnostic and interventional neuroradiology.⁵

An ICU run within the same hospital must be available when needed.

ESO Stroke Centers should have immediate access to cardiological expertise.^{59,60} This implies consultation of a cardiologist and the availability of transesophageal echocardiography on-site on a 24/7 basis.

Additional Diagnostics

Additionally, the following upper level diagnostics and procedures are required like:

1. ≥ 64 slices CT scanner,
2. 24/7 CT, perfusion CT, CT angiography, MR (including diffusion weighted imaging, perfusion weighted imaging, MR angiography), and
3. 24/7 availability of upper level diagnostics and care in the center of neurosurgery, vascular surgery, interventional neuroradiology, and cardiology.

Interventional Procedures

Intra-arterial interventions (intra-arterial thrombolysis and mechanical thromboendarterectomy) available 24/7.

Role as Referral Center

ESO Stroke Centers should serve as a referral center (HUB) for peripheral hospitals, including ESO Stroke Units and also telemedical consultations. Telemedicine is an option for widening access to organized stroke unit care. Cooperations with ESO Stroke Units must be documented by pathways.

Clinical Research

The ESO stroke center should serve as a platform for stroke research with stroke study coordinators operated by a stroke

faculty. Staff should take part in randomized controlled trials and apply for research grants.

Quality Indicators, Quality Management, and Benchmarking

The practical documentation of the quality of stroke care is routinely guaranteed by

1. the multidisciplinary meeting group once a week and documentation in a logbook that each stroke patient was discussed by the multiprofessional team at least once,
2. the organization of an annual teaching course for nurses and nonmedical staff,
3. the availability of a written stroke care protocol for acute stroke intervention and standard stroke management, including the prehospital phase, emergency department care, acute treatments, monitoring, early neurorehabilitation, discharge planning, and posthospital follow-up, and
4. the availability of a written care protocol for early secondary stroke prevention according to most recent European Stroke Organisation Guidelines.⁵

A local stroke register assessing age, sex, initial stroke severity, thrombolysis, and discharge data (discharge disposition, mortality, and quality indicators listed below) for benchmarking is recommended.

Every stroke unit should also enter its individual patient data into a regional or national databank (at least on the level of the catchment area or state or country) allowing the benchmarking of the following quality indicators consented during a Delphi-like process.^{12,13} These quality indicators have recently been revised.

This ESO Stroke Unit Committee agreed to the following 6 quality indicators of organized stroke care as compulsory:

1. Percent of acute stroke patients treated with intravenous thrombolysis having a door-to-needle time <60 minutes.
2. Percent of all acute patients with stroke as the predominant pathology admitted to the hospital treated on the stroke unit (or the ICU, if appropriate).
3. Percent of brain imaging by CT or MRI in every suspected stroke.
4. Percent of ischemic stroke patients with antithrombotic therapy (antiplatelet medication) at discharge.
5. Corresponding antithrombotic therapy (anticoagulation) at discharge in patients with atrial fibrillation.
6. Percent of stroke unit patients screened for swallowing disorders.

The following additional 7 quality indicators were considered compulsory by the ESO Stroke Unit Committee. Every ESO Stroke Unit/Stroke Center should at least work on 3 of the following items:

7. Vascular imaging in patients with ischemic stroke or TIA.
8. Early brain imaging within 1 hour of admission in patients arriving within 2 hours after stroke onset.
9. Percentage of eligible patients receiving intravenous thrombolytic therapy.
10. Carotid revascularization for $\geq 50\%$ symptomatic carotid stenosis (according to North American Symptomatic Carotid Endarterectomy Trial (NASCET)-criteria).

11. Statin treatment at the end of hospital stay in atherothrombotic ischemic strokes.
12. Antihypertensive treatment at the end of hospital stay for hypertensive patients.
13. Prehospital awareness and training program for laypersons and medical personnel aiming at rapid recognition of stroke signs and immediate emergency admission to a stroke unit/stroke center.

Although several audits for monitoring quality of stroke care have been established in Europe, there is currently no consensus on quality indicators for acute stroke care or for methodology for collecting information on these measures. At present, it is not possible to provide specific targets for these quality indicators⁶¹. However, the selected panel may serve as a basis to implement a European quality indicator set and to elaborate step-by-step future target ranges. The severity of stroke on admission and the age and sex of the patient are the most important determinants of stroke outcome. Therefore, it is absolutely necessary to know the case-mix for estimation of outcome, for correction of case-mix in outcome evaluation, for quality control measurements and for benchmarking.^{62,63} To facilitate this task, this Committee suggests that the ordinary hospital patient data set run by the administrator should incorporate these items for benchmarking.

Follow-up of patients after their acute stroke unit treatment is recommended at an outpatient clinic to assess the outcome of stroke unit care and to ensure that the patients receive appropriate secondary prevention. Three- or 6-month follow-up is encouraged but not compulsory.

Glossary

Stroke Unit

A dedicated, geographically clearly defined area or ward in a hospital, where stroke patients (according to the above-defined target population) are admitted and cared for by a multiprofessional team (medical, nursing, and therapy staff) who have specialist knowledge, training, and skills in stroke care with well-defined individual tasks, regular interaction with other disciplines, and stroke leadership. This team shall coordinate stroke care through regular (weekly) multiprofessional meetings.

Stroke Ward Versus Stroke Unit

The stroke ward is the physical location with an arrangement of specially equipped beds in a circumscribed area of the hospital, where exclusively stroke patients are treated. A stroke unit requires a stroke ward but also specialized multiprofessional staff realizing all the processes described in this paper.

A stroke unit is not a stand-alone unit that operates within a hospital delivering intravenous tissue plasminogen activator, imaging, etc. A stroke unit can also operate outside a stroke center. These 2 infrastructures are, however, usually connected.

According to the ESO recommendations, we propose a stroke unit which is not a stand-alone unit but tightly woven into the hospital infrastructure. A stroke unit should be staffed

with a multiprofessional team, including stroke physician, stroke nurses, physiotherapists, speech therapists, occupational therapists, social workers, and neuropsychologists (if the latter is available). Radiology services must be available on 24/7 basis but are not a direct part of the stroke unit itself. The same applies to the emergency department or emergency room. There has to be one within the hospital, but it does not need to be a part of the stroke unit. Intravenous tissue plasminogen activator must be available, and the door-to-needle time aim is <60 minutes. Patients with large intracranial hemorrhage and subarachnoid hemorrhage will be stabilized and transferred to the department of neurosurgery when appropriate, or, if neurosurgery is not indicated, treated conservatively in the stroke unit.

Stroke Center

A hospital infrastructure and related processes of care that provide the full pathway of stroke unit care. A stroke center is the coordinating body of the entire chain of care. This covers prehospital care, emergency room assessment and diagnosis, emergency medical treatment, stroke unit care, ongoing rehabilitation and secondary prevention, and access to related neurosurgical and vascular intervention. A stroke unit is the most important component of a stroke center. ESO Stroke Center provides stroke unit services for the population of its own catchment area and serves as a referral center for peripheral hospitals with ESO Stroke Units in case their patients need services that are not locally available.

Comprehensive Stroke Unit Care

This term is used here in the sense that acute medical care is delivered in conjunction with early mobilization and rehabilitation by the multiprofessional stroke unit team. This type of organization is a requirement for both ESO Stroke Unit and ESO Stroke Center.

Sources of Funding

The European Stroke Organisation (ESO) provided reimbursement for working meetings of the ESO Stroke Unit Committee

Disclosures

Vincent Thijs has declared to have received modest support from Boehringer Ingelheim (Speakers' Bureau) and from Boehringer Ingelheim, Sygnis, Bayer, and Pfizer (Consultant/Advisory Board). The other authors have no conflicts to report. The ESO does not have any financial interest to declare regarding this proposal. Indeed, the process of certification would come with a cost to the stroke unit center, but these royalties would be paid to an independent, professional provider of certification technology. It is not clear yet, however, whether the ESO itself will participate financially. If at all, this should be only to a minor part covering the direct costs of the ESO for traveling and meetings of the ESO Stroke Unit Committee. There would not be a problem in declaring a potential conflict of interest in case that the ESO would participate in any financial issues of the certification process in the future. At present, ESO has estimated that the price of evaluation leading to the certification is about 5000 Euros, which should not prevent many hospitals from seeking it. In countries which already have their own stroke unit certification, ESO certification could contribute to a future harmonization and improvement. The ESO has no intention to put any

sanctions on stroke units not applying for, or not passing the certification process.

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KEY WORDS: criteria for stroke unit care ■ European Stroke Organisation
■ ESO Stroke Unit ■ ESO Stroke Center ■ organized stroke unit care